9. GENERAL DESCRIPTION AND CONCEPTUAL DESIGN OF TRIM.Risk

The National Academy of Sciences (NAS) has defined risk characterization as a description of the nature and magnitude of human or ecological risk and the attendant uncertainties (NRC 1983). Risk characterization is the final step in risk assessment and is primarily used to integrate the information from the other three key steps (*i.e.*, hazard identification, dose-response assessment, exposure assessment). Within the TRIM framework, the risk characterization module (TRIM.Risk) will be used to integrate the information on exposure (to human and ecological receptors) with that on dose-response or hazard and to provide quantitative descriptions of risk and the attendant uncertainties. The TRIM.Risk module will provide decision-makers and the public with information for use in developing, evaluating, and selecting appropriate air quality standards and risk management strategies. The sources of input data for TRIM.Risk can be other TRIM modules, including model assumptions, inputs, and results, or outside information sources or models.

9.1 BACKGROUND ON RISK CHARACTERIZATION

In general, the Agency's risk characterization guidance described below addresses two essential elements of a full characterization of risk. First, the characterization should address qualitative and quantitative features of the assessment. That is, in addition to quantitative estimates of risk, a full risk characterization should clearly describe (1) the hazard information and associated relevant issues, (2) the dose-response relationship used, and (3) what is known about the principal paths, patterns, and magnitudes of exposure. Furthermore, for each of these three items, the characterization should describe any assumptions, the rationale behind these assumptions, and the effect of reasonable alternative assumptions on the conclusions and estimates. The second essential element of a full risk characterization is the identification and discussion of any important uncertainties. As noted by the Agency's Deputy Administrator in issuing the Agency's initial risk characterization policy memo "... scientific uncertainty is a fact of life (and) ... a balanced discussion of reliable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment..." The uncertainty discussion is important for several reasons (Habicht 1992):

- Information from different sources carries different kinds of uncertainty, and knowledge of these differences is important when uncertainties are combined for characterizing risk, allowing for decisions to be made about expending resources to acquire additional information to reduce the uncertainties; and

- Uncertainty analysis provides the decision-maker and the public with clear and explicit statements of the implications and limitations of a risk assessment and of the related uncertainties.

Each step of the analysis phase of risk assessment (*i.e.*, hazard identification, dose-response assessment, exposure assessment) should include its own summary characterization section. Because every risk assessment has many uncertainties and involves many assumptions, the challenge in characterizing risk for decision-makers, whose time is limited and who may not be risk experts, is to convey that small subset of *key* strengths and limitations that are crucial to the assessment outcome. When integrated, they identify the fundamental, irreducible set of key points that must be communicated to characterize adequately any risk assessment. Therefore, the risk characterization should provide the following:

- A clear description of the key strengths and weaknesses;
- A brief "bottom-line" statement about the risks, including the assessor's confidence in any estimate(s) of risk and in the conclusions; and
- Information that allows the reader to grasp easily what is known about the nature, likelihood, and magnitude of any risk.

For each step of the analysis phase of risk assessment, the assessor should identify the following items:

- Available studies and their robustness (*e.g.*, have the findings been repeated in an independent laboratory?);
- Assumptions and extrapolations used and the residual uncertainties;
- Use of defaults, policy choices, and any risk management decisions;
- Quality of the data used for the risk assessment (*e.g.*, experimental, state-of-the art, generally accepted scientific knowledge); and
- Quantitative data presented in an easily understandable form, such as tables and graphics.

At EPA, risk characterization takes many different forms depending on the nature of the risk assessment. The level of detail in each risk characterization varies according to the type of assessment for which the characterization is written and the audience for which the characterization is intended. The goal of risk characterization is to clearly communicate the strengths and limitations of the risk assessment so it can be put into context with the other information critical to evaluating options for rules, regulations, and negotiated agreements (*e.g.*, economics, social values, public perception, policies) in the decision-making stage.

The general content of risk characterization is defined by the NAS and, to a limited degree, in each of the EPA risk assessment guidelines (*e.g.*, U.S. EPA 1996a). More specifically, however, the Agency issued its first policy for risk characterization in 1992 (Habicht 1992). This policy was intended to strengthen the reporting of the Agency's risk assessment results. Previously, risk information was sometimes presented to the decision-maker and the public in a form reduced to a simple point-estimate of risk. Such "short-hand" approaches did not fully convey the range of information used in developing the assessment because the numbers alone do not provide an accurate picture of the assessment.

More recently, the Agency updated its policy and issued guidance for the preparation of risk characterizations (Browner 1995, U.S. EPA 1995a, U.S. EPA 1995b). The policy called for all risk assessments performed at EPA to include a risk characterization to ensure that the risk assessment process is transparent and that the risk assessments are clear, reasonable, and consistent with other risk assessments of similar scope prepared by programs across the Agency. In issuing the policy and guidance, the Administrator emphasized the importance of a set of core values to guide risk characterization activities. These core values are transparency, clarity, consistency, and reasonableness (TCCR).

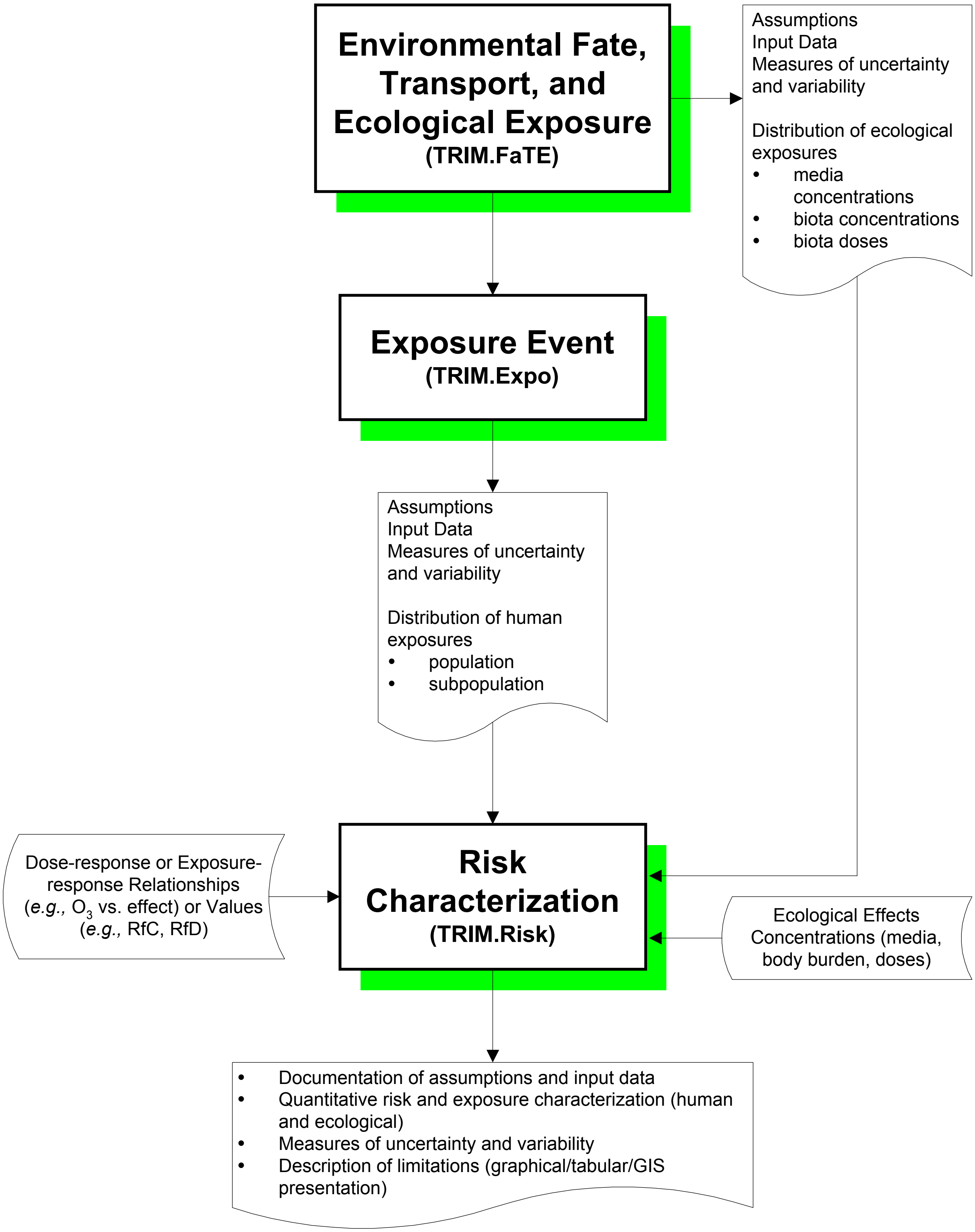
To implement the policy, an Agency-wide document, the *Risk Characterization Handbook*, is being developed (U.S. EPA 1998c). The previously issued policy and guidance, as well as the *Risk Characterization Handbook* under development, will be used to guide the design and implementation of the TRIM.Risk module. Therefore, this chapter includes text drawing from specific discussions and recommendations outlined in these documents along with a description of how TRIM.Risk will conceptually address these recommendations.

9.2 PURPOSE OF TRIM.Risk

In order to develop a full risk characterization, information from each of the risk assessment components needs to be characterized separately. These individual characterizations carry forward the key findings, assumptions, strengths, and limitations, and provide a fundamental set of information that must be conveyed in an informative risk characterization. The purpose of the TRIM.Risk module is to summarize and integrate key information from other TRIM modules in addition to other information sources (Figure 9-1) and to facilitate the preparation of a risk characterization. In general, TRIM.Risk will (1) document assumptions and input data, (2) perform risk calculations and data analysis, and (3) present results and supporting information. Where possible, these actions will be automated. It should be noted that while TRIM.Risk is the module with the primary purpose of preparing information to support risk characterization, the guiding principles for risk characterization are also being followed in the development of other TRIM modules (*e.g.*, documenting setup, runs, output), which will facilitate the development of TRIM.Risk.

It is anticipated that TRIM.Risk will be developed in a phased approach similar to other TRIM modules. Ideally, the TRIM.Risk module will provide all of the information required to prepare a full risk characterization. However, the type and variability of information needed for this purpose is vast. Therefore, the type of information generated by TRIM.Risk will evolve over time as the Agency gains experience and has the resources to implement more flexibility. For example, early versions of TRIM.Risk will be limited to preparing quantitative summaries of input data and results, without supporting text. However, as the Agency gains experience, it may be possible to incorporate language to more fully describe the information required for a full risk characterization.

Figure 9-1
Conceptual Diagram of the TRIM.Risk Module



The purpose of TRIM.Risk is to provide information to risk managers, the public, and stakeholders to support decision-making. To be effective, TRIM.Risk must communicate information that is readily understandable. Specifically, TRIM.Risk is responsible for conveying the information for a specific risk assessment. However, because risk assessments are often used to inform choices between policy alternatives, care will be taken to insure that outputs from TRIM.Risk are formatted to facilitate comparisons (including statistical comparisons) between alternatives.

9.3 DESIGN GOALS OF TRIM.Risk

As described in Chapter 1, EPA has established specific goals for the design of TRIM which can be used to measure progress and performance of either the overall modeling system or its individual components. These overall design features of scientific defensibility, flexibility, and accessibility (user-friendliness) apply to the TRIM.Risk module as well. How TRIM.Risk will meet these major design goals is summarized below.

- *Scientific defensibility*. The scientific defensibility of TRIM.Risk will be assured by adherence to the applicable risk characterization guidance (U.S. EPA 1995a, U.S. EPA 1998c) and by full utilization of the abilities of the other TRIM modules to describe uncertainty and variability surrounding their outputs. Consistent with the Agency's guidance for risk characterization to clearly communicate the key strengths and weaknesses of any assessment, the TRIM.Risk module will have the capability to present the variety of important information generated by any of the other TRIM modules. The capability of addressing uncertainty and variability in an integrated manner is critical to presenting risk information beyond deterministic single-point estimates of risk, which is essential in a full characterization of risk. Furthermore, the integrated uncertainty and variability analysis capabilities of the TRIM modules also enhance the ability to identify critical assumptions and data and determine their contributions to overall uncertainty.

- *Flexibility*. The flexibility designed within the TRIM framework will be maintained in TRIM.Risk. Specifically, TRIM.Risk will accommodate and present information for the variety of spatial and temporal scales of analysis possible for other TRIM modules. The value of any risk characterization lies in its ability to convey useful and, most importantly, understandable information to risk managers. An OAQPS evaluation of information needs of risk managers found that because different people process information differently, it is appropriate to provide more than one format for presenting the same information (U.S. EPA 1993). As a result, TRIM.Risk will be designed in such a way that using a specific user interface, outputs may be presented in user-specified formats (*e.g.*, tables, charts, graphics).

- *Accessibility*. As with all TRIM modules, TRIM.Risk will be publicly available and easily obtainable by all interested parties, along with user guides, and will be designed to be user-friendly.

9.4 OVERVIEW OF TRIM.RISK

Current and proposed EPA guidance on risk characterization are serving as the basis for designing TRIM.Risk. Therefore, the major elements identified in the guidance with respect to TCCR will be explicitly addressed in TRIM.Risk and are described below. In addition, some discussion is provided on how TRIM.Risk will provide such information and conduct its three primary functions: (1) documenting assumptions and input data, (2) risk calculation and data analysis, and (3) presentation of results.

9.4.1 DOCUMENTATION OF ASSUMPTIONS AND INPUT DATA

One purpose of a full risk characterization is to inform the risk manager and others of why EPA assessed the risk the way it did in terms of the available data, the analysis used, uncertainties, alternative analyses, and science policy choices. Risk characterization is not only about science, but also about making clear that current scientific knowledge does not provide all that is needed to perform the analysis, and consequently science policy judgments must be made. Every risk assessment involves a multiplicity of choices and options, and the Agency's *Policy for Risk Characterization* (U.S. EPA 1995b) calls for a highly visible presentation of the explanation for these choices. When appropriate, a recognition and discussion of how others have assessed the same risks should be included.

The computer framework of TRIM (described in Chapter 10) provides an excellent opportunity for documenting assumptions and input data. The algorithm library and parameter database approach used in the TRIM.FaTE and TRIM.Expo modules allows for easy documentation of the algorithms and parameters used in an analysis. Although each module contains default inputs and algorithms, the user can replace these values with alternatives to support site-specific analysis or alternative assumptions. To provide transparency in interpreting results, the TRIM modules will be self-documenting (see Chapter 10), with the ability to catalog the data and algorithms used for every model run, thereby identifying any changes in parameters or algorithms. Therefore, it can be readily determined if differences between model runs are attributable to differences in parameters or algorithms. The algorithm library and parameter database also have comment fields, which provide the opportunity for articulating the rationale for such changes. In addition, the design of user interfaces for each model run within individual modules will document the major assumptions of the analysis.

9.4.2 RISK CALCULATION AND ANALYSIS

A variety of risk calculations and analyses is performed by the Agency in risk assessments for the hazardous and criteria air pollutant programs. The TRIM.Risk module is intended to perform this full spectrum of analyses to support characterizations of both human health and environmental risks.

9.4.2.1 Human Health Risks

Because cancer and noncancer dose-response assessment have traditionally been different (*i.e.*, assumption of threshold for noncancer versus no threshold for cancer), the current methods for risk assessment also differ and are discussed separately below. In some cases, available data and information do not support the estimation of quantitative estimates of risk. In those cases, the risk characterization may rely on data analyses that summarize risks in a semi-quantitative or qualitative manner, such as comparing exposure concentrations to exposure levels of concern.

Quantification of Cancer Risks

Cancer risk is defined as the predicted excess probability of contracting cancer over a 70-year period (*i.e.*, assumed human lifespan) following exposure to a pollutant at the estimated concentration for a specified time period. This estimated risk focuses on the additional risk of cancer predicted from the exposure being analyzed, beyond that due to any other factors. Individual cancer risks or population cancer risks associated with an exposure can be calculated by multiplying the individual or population exposure estimate, respectively, by the unit risk estimate (URE). Estimates of risk to an individual are usually expressed as a probability represented in scientific notation as a negative exponent of 10. For example, an additional risk of contracting cancer of one chance in 10,000 (or one additional person in 10,000) is written as $1x10^{-4}$.

In quantitative risk assessment, population risk is an estimate that applies to the entire population within the given area of analysis. The population risk often is expressed as a predicted annual cancer incidence, which is the annual number of excess cancer cases predicted in the exposed population. Each estimated exposure level is multiplied by the number of individuals exposed to that level and by the URE. This provides a prediction of risk for that group after a 70-year exposure to that level. The risks for each exposure group are summed to provide the number of excess cancer cases predicted for the entire exposed population. This 70-year risk estimate can be divided by 70 to estimate the predicted annual incidence in units of cancer cases per year.

People often are exposed to multiple chemicals rather than a single chemical. For analysis of cancer risk from multiple chemical exposures, TRIM.Risk will be consistent with the Agency's *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA 1986a). In developing TRIM.Risk, activities to update these guidelines (*e.g.*, U.S. EPA 1999c) will be followed closely to ensure consistency.

In those few cases where cancer potency values are available for the chemical mixture of concern or for a similar mixture, risk characterization can be conducted on the mixture using the same procedures used for a single compound. However, cancer dose-response assessments usually are available only for individual compounds within a mixture. In such cases, based on the assumption that the risks associated with the individual chemicals in the mixture are additive, the cancer risks predicted for individual chemicals are sometimes added to estimate total risk. The following equation estimates the predicted incremental individual cancer risk for simultaneous exposures to several carcinogens:

$$Risk_T = Risk_1 + Risk_2 + ... + Risk_i$$

where:

$Risk_T$ = the total cancer risk (expressed as a probability of contracting cancer over a lifetime)
$Risk_i$ = the risk estimate for the i^{th} substance.

As described in the proposed revisions to the guidelines for carcinogen risk assessment (U.S. EPA 1996b), when sufficient information is known on the mode of action for a pollutant, dose-response may be better defined by a non-linear relationship. In cases of non-linearity, risk is not extrapolated as the probability of an effect at low doses. In these cases, a margin of exposure analysis is used to evaluate concern for levels of exposure. The margin of exposure is the "point of departure" from the health effects data divided by a human environmental exposure(s) of interest – either actual or hypothetical. Exposures may be of interest because they are associated with actual or projected exposure scenarios or because they are levels that may result from alternative control actions. The risk manager decides whether a given margin of exposure is acceptable within a given regulatory program context. The risk assessment provides an analysis with supporting information and advice to assist the decision-maker in considering aspects of the exposure scenarios at issue in light of the mode of action. A margin of exposure analysis presents all of the pertinent hazard and dose-response factors together. The TRIM.Risk module will be designed to provide analyses and output consistent with the revised guidelines for carcinogen risk assessment.

Analysis of Noncancer Risks

Unlike cancer risk characterization, noncancer risks for hazardous air pollutants currently are not expressed as a probability of an individual suffering an adverse effect (*e.g.*, reproductive, neurological, behavioral). Instead, the potential for noncancer effects often is evaluated by comparing an exposure estimate over a specified period of time (*e.g.*, lifetime) with a health reference value, such as a reference concentration (RfC). "Risk" for noncancer effects is quantified by comparing the exposure to the reference level (or benchmark) as a ratio. The resultant Hazard Quotient (HQ) is expressed as:

$$HQ = Exposure/Benchmark.$$

Exposures or doses below the benchmark ($HQ<1$) are not likely to be associated with adverse health effects. With exposures increasingly greater than the reference level (*i.e.*, HQs increasingly greater than 1), the potential for adverse effects increases. The HQ, however, should not be interpreted as a probability. Comparisons of HQs across substances may not be valid, and the level of concern does not increase linearly as exposures approach or cross the reference level. This is because reference levels are derived using different methods and because the slope of the dose-response curve above the benchmark can vary depending on the substance.

As with the evaluation of cancer risks described above, analysis of mixtures in TRIM.Risk will be consistent with Agency guidelines (U.S. EPA 1986a, U.S. EPA 1999c). In screening-level assessments for such cases, a Hazard Index (HI) approach is sometimes used. This approach is based on the assumption that even when individual pollutant levels are lower than the corresponding reference levels, some pollutants may work together such that their potential for harm is additive and the combined exposure to the group of chemicals poses harm. The assumption of dose additivity is most appropriate to compounds that induce the same effect by similar modes of action (U.S. EPA 1986a). The HI (for a mixture of *i* compounds) is calculated as:

$$HI = HQ_1 + HQ_2 + ...+ HQ_i.$$

As with risk measures for individual pollutants, the HI should not be interpreted as a probability of effect, nor as strict delineation of "safe" and "unsafe" levels (U.S. EPA 1999f, U.S. EPA 1986a). Rather, the HI is a rough measure of potential for risk and needs to be interpreted carefully. Although the HI approach may be appropriate for a screening-level study (U.S. EPA 1999f), it is important to note that application of the HI equation to compounds that may produce different effects or that act by different mechanisms could overestimate or underestimate the potential for effects. Calculating a separate HI for each noncancer endpoint of concern when mechanisms of action are known to be the same is scientifically more appropriate (U.S. EPA 1999f, U.S. EPA 1986a).

It should be noted that, in some instances, the noncancer toxicity of a particular pollutant is well characterized, either because the biokinetics and toxicokinetics are well known or because substantial information on dose- or exposure-response relationships are well known. In these circumstances, probabilistic risk estimates similar to those described for cancer risks above may be possible. For example, risk assessments for criteria air pollutants, and potentially future risk assessments for hazardous air pollutants, utilize a variety of dose- or exposure-response tools in place of the RfC or RfD values. For example, risk assessments for carbon monoxide (CO) include a step in which a population distribution of response (*i.e.*, carboxyhemoglobin production in the blood) is modeled from the population distribution of CO exposures. In ozone risk assessments, population distributions of exposure are modeled against an exposure-response relationship (derived from either controlled human exposures or epidemiological analyses) to predict the distribution of responses in the exposed population or subpopulation. In the case of lead risk assessments, exposure estimates are entered into the IUBK (Intake, Uptake, Biokinetic) model to predict blood levels of lead, which can be compared to levels of concern in the risk characterization step.

9.4.2.2 Environmental Risk

Some components of environmental risk assessment are integral to the assessment of human health risks. For example, the concentrations of pollutants in the environment and their fate and transport can represent a significant part of human exposure assessment. In addition, laboratory animal toxicity data are often used to extrapolate effects of chemical exposures on humans. However, because ecosystems consist of living and non-living entities linked together in numerous interdependent relationships, the scope of an environmental risk assessment can range from very simple to very broad and complex and must be defined at the outset. As an assessment moves from the level of the individual organism to species or populations of species, communities of several species, and to whole ecosystems, the level of complexity increases. To an even greater degree than for human health, environmental risk assessments rely on qualitative information or expert judgments.

*Individual and Population Level*s

When the scope of an environmental risk assessment is set at the level of an individual organism within a species or an entire population or subpopulation of that species (*e.g.*, threatened or endangered species, sentinel species), the assessment may use types of information and tools analogous to those used for human health risk assessments. In some cases, animal toxicity data developed for human health risk assessments may be directly applicable to the animal species of concern (*e.g.*, when species-specific toxicity values, such as EC_{50}, EC_{10}, LC_{50}, NOAEC, LOAEC, MATC, already exist).

The TRIM.Risk module will have the ability to compare these ecological toxicity values or endpoints with the outputs of TRIM.FaTE (or another source of data) – including (1) concentration of pollutant in relevant media, such as air, soil, water, sediments, (2) tissue concentrations or body burdens in organisms based on ingestion, dermal contact or absorption, or inhalation, and (3) the dose or amount entering organism per unit time. This information can then be used to derive hazard quotients or display the distributions of exposures relative to toxicity values or endpoints.

Because of the paucity of ecological toxicity data for most species, however, extrapolation from one species to the other and from laboratory to field conditions is required, introducing significant uncertainties into the calculation of risk. With respect to animals, a primary effect of concern is mortality. However, because most ecological species live in a much more competitive environment than humans, noncancer effects (*e.g.*, reproductive, neurological, behavioral, growth) can also play a large role in individual and species survival (*e.g.*, reduced ability to avoid predators, defend territory, attract a mate), though they are much more difficult to measure.

Because populations are made up of individual organisms, if enough individuals of a species are adversely affected by exposure to a chemical, the population also will be adversely affected. In order to evaluate population effects from data on individuals, it is necessary to know what kind of life history strategy is employed by that species. In addition to direct effects of exposure, an organism may be indirectly affected by the presence of a toxic chemical in the environment (*e.g.*, through effects on a prey species or on some other aspect of the environment that reduces habitat quality). The EPA's water quality criteria for the protection of aquatic life are an example of an indicator as to the suitability of the aquatic habitat for certain species as well as providing information to assist in the evaluation of the potential for ecosystem impacts.

As with humans, other species are often exposed to multiple chemicals simultaneously or in close temporal proximity so that there may be interactions occurring between them (*e.g.*, synergistic effects, antagonistic effects). Although little is known about these interactions in the field, where information does exist for chemical mixtures, it can be used in the same way as that for a single compound. Where information does not exist about chemical interactions, it may be necessary to make assumptions in order to assess the risk posed by mixtures.

Communities and Whole Environments

Although TRIM.Risk will have the ability to provide distributions of hazard quotients around the modeled site for species of concern, it is expected that substantial additional information will be needed in order to sufficiently characterize risks occurring from HAP exposure at the community and ecosystem levels. Such a refined analysis may require information such as detailed descriptions of the particular ecosystem in which the exposures are occurring; the temporal and spatial scales of the exposures; the significance of the effect of the exposure in the larger landscape; and the ecosystem services and functions affected. Some of this information may be available from TRIM.FaTE or by accessing GIS databases. Thus, the complete ecological risk characterization would combine the outputs of TRIM.Risk with other relevant information in a weight-of-evidence approach.

9.4.3 PRESENTATION OF RESULTS

As stated above, there are two elements required for a full characterization of risk. First, the characterization must address qualitative and quantitative features of the assessment, namely clearly identify assumptions (covered under documentation of assumptions and inputs above) as well as quantitative estimates of risk. Second, the characterization must identify any important uncertainties in the assessment as part of a discussion on confidence in the assessment. TRIM.Risk, in presenting results, will address these two points.

9.4.3.1 Risk Descriptors for Human Health

The Agency's *Guidance for Risk Characterization* (U.S. EPA 1995a) recommends that EPA risk assessments address or provide descriptors of (1) individual risk, to include the central tendency and high-end portions of the risk distribution, (2) population risk, and (3) important subgroups of the populations such as highly exposed or highly susceptible groups or individuals, if known. Assessors may also use additional descriptors of risk as needed when these add to the clarity of the presentation. With the exception of assessments where particular descriptors clearly do not apply, some form of these three types of descriptors should generally be developed and presented for EPA risk assessments.

- **Individual Risk.** Individual risk descriptors are intended to estimate the risk borne by individuals within a specified population or subpopulation. These descriptors are used to answer questions concerning the affected population, the risk levels of various groups within the population, and the average or maximum risk for individuals within the populations of interest.

- **Population Risk.** Population risk descriptors are intended to estimate the extent of harm for the population as a whole. This typically represents the sum of individual risks within the exposed population. Two important population risk descriptors should be estimated and presented (Habicht 1992): (1) the probabilistic number of health effect cases estimated in the population of interest over a specified time period; and (2) the percentage of the population, or the number of persons, above a specified level of risk or range of health benchmark levels.

- **Highly Exposed or Highly Susceptible Subpopulations.** Risk descriptors also may be developed for specific segments of the exposed population. These include highly exposed and highly susceptible groups (U.S. EPA 1995a). Use of a risk descriptor for highly exposed subgroups is useful when there is expected to be a subgroup experiencing significantly greater exposures than those of a larger population (*e.g.*, high fish consumers, children playing outdoors all day). Use of a risk descriptor for highly susceptible subgroups is useful when the susceptibility to the health effect being assessed is expected to be significantly greater for a specific population subgroup than it is for the larger population. For example, upon exposure to a chemical, pregnant women, elderly people, children, and people with certain illnesses or nutritional status may each be more sensitive than the population as a whole.

Consistent with Agency guidance, TRIM.Risk will provide central tendency and high-end estimates of risk. Use of several descriptors, rather than a single descriptor, will result in a more complete picture of risk that corresponds to the range of different exposure conditions encountered by various populations exposed to most environmental chemicals. Central tendency estimates of risk are intended to give a characterization of risk for the typical situation in which an individual is likely to be exposed. This may be either the arithmetic mean risk (*i.e.*, average estimate) or the median risk (*i.e.*, median estimate) and should be clearly labeled (Habicht 1992). High-end estimates of risk are intended to estimate the risk that is expected to occur in a small but definable segment of the population. The intent is to "convey an estimate of risk in the upper range of the distribution, but to avoid estimates which are beyond the true distribution. Conceptually, high-end risk means risk above about the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk" (Habicht 1992).

9.4.3.2 Presentation of Ecological Risk Assessment Results

In the problem formulation stage of ecological risk assessment, the specific analyses that will be performed for the assessment are identified. Depending on how these analyses are framed, the assessment could focus on either population risk or ecosystem risk. The TRIM.Risk module will be designed with the flexibility for the user to specify the focus of the assessment and the relevant risk analyses. The results will be presented in a form relevant to the specific focus (*e.g.*, a presentation of population risk or ecosystem risk information).

To present outputs for ecological risk, in some cases (*e.g.*, with endangered or indicator species) HQs may be useful by themselves, where the distribution of HQs may be graphically displayed on a map of the study area. In most cases, however, a weight-of-evidence approach will be needed. In these cases, a suite of GIS maps showing different layers of information could be used by experts to evaluate the meaning and context of the HQ. These GIS maps might include media concentrations for both single and multiple HAPs, land use, terrain/topography, soil types, hydrology, distributions of flora/fauna, distributions of endangered species, and temporal variations (*e.g.*, between years, seasons). In the case of contamination by or exposure to multiple HAPs, GIS overlays might help with the identification of ecological "hotspots" that might not be identified by evaluating the pollutants separately. In addition to GIS maps, graphical displays of distributions of effects within a population would be useful. In cases where TRIM.Risk is used for a simple screening exercise, site-specific information would not be needed and TRIM.Risk can provide more simple outputs.

9.4.3.3 Uncertainty

Uncertainty can be introduced into a risk assessment at every step in the process. Even using the most accurate data with the most sophisticated models, uncertainty is inherent in the process because risk assessment is a complex process. The degree to which all types of uncertainty need to be quantified and the amount of uncertainty that is acceptable vary, depending on the purpose and intended use of the risk assessment. For a screening-level analysis, a high degree of uncertainty often is acceptable, provided that conservative assumptions are used to bias potential error toward protecting human health or the environment. Similarly, the concentrations at a specific location in a region-wide or nationwide assessment will be more uncertain than the concentrations at a specific location in a site-specific assessment because there is more variability in the input parameters for larger scale assessments.

9.4.3.4 Outputs

Because there is more than one audience for each risk assessment, there will probably be more than one risk characterization for a risk assessment. Different types of risk assessment also vary in length and degree of detail, and each risk characterization is as simple or complex as the assessment from which it is derived. While the full risk characterization is written for the type of assessment conducted, as it is presented to various audiences, the characterization product should be tailored to that audience. For fellow risk assessors and other scientists, the full characterization is most appropriate. If the risk characterization is presented to non-technical colleagues and to those whose time is limited (*e.g.*, managers), it should shortened and focused, but the characterization should always include the fundamental, irreducible set of key points that must be communicated to characterize adequately the essence of any risk assessment.

OAQPS recognizes that individuals process information differently and it is, therefore, appropriate to provide more than one format for presenting the same information. Therefore, each TRIM module will be designed so that the output can be presented in various ways in an automated manner (*e.g.*, Chart Wizard in Excel), allowing the user to select a preferred format.

The TRIM.Risk module will provide quantitative estimates of risk for both human and ecological risks. At a minimum, the following risk measures will be presented as outputs of TRIM.Risk.

EXAMPLES OF RISK MEASURES TO BE INCLUDED IN TRIM.Risk

Human Risks		
	Cancer	Distributions of excess cancer, MOE within exposed population (Note: deterministic values may be used for screens) Estimate of predicted cancer incidence
	Noncancer	Distribution of HQ or HI within exposed population (Note: deterministic values may be used for screens) Distribution of exposure (dose) relative to exposure (dose) levels of concern Distribution of probability of effect within exposed population (estimated incidence)
Ecological Risks		Distribution of concentration/criteria (similar to HQ or HI) Distribution of probability of effect within population

9.5 CURRENT STATUS AND FUTURE PLANS FOR TRIM.Risk

At present, only the conceptual design of TRIM.Risk has been developed. Development of a TRIM.Risk prototype will begin after SAB comments are received on the conceptual design. Module development will include identification of data needs and formatting of data outputs. Programming for a TRIM.Risk prototype is expected to be completed in 2000.